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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PINAKI RAY

Appeal 2009-015369
Application 09/475,768
Technology Center 3700

Before JENNIFER D. BAHR, STEFAN STAICOVICI and
MICHAEL L. HOELTER, *Administrative Patent Judges*.

HOELTER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

This is a decision on appeal, under 35 U.S.C. § 134(a), from a final rejection of claims 1-13 and 48-64. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

The Claimed Subject Matter

The claimed subject matter pertains to delivery and collection conduits used to isolate the fluid (i.e. blood) flowing to/from a biological mass such as a heart, kidney, liver or brain; the collection conduit having a seal for occluding the downstream channel. Independent claim 1 is illustrative of the invention and is reproduced below:

> 1. A system for fluid isolation in a biological mass having at least one upstream channel and at least one downstream channel, comprising:
>
> a delivery conduit for administering a fluid to the biological mass, the delivery conduit having a length dimension suitable to be positioned from a first externally accessible channel of a patient adjacent to or into at least one upstream channel of the biological mass by way of a percutaneous trans luminal route; and
>
> a collection conduit for acquiring the administered fluid, the collection conduit having a length dimension suitable to be positioned from a second externally accessible channel of a patient adjacent to or into at least one downstream channel of the biological mass by way of a percutaneous transluminal route and having a collection seal having a dimension, in one configuration, to occlude the at least one downstream channel;
>
> wherein the biological mass is selected from the group consisting of a heart, a portion of a heart, a kidney, a portion of a kidney, a stomach, a liver, and a brain.

References Relied on by the Examiner

Boddie	US 4,192,302	Mar. 11, 1980

Aigner	US 4,540,402	Sep. 10, 1985
Sterman	US 5,452,733	Sep. 26, 1995

The Rejections on Appeal

1. Claims 1-9, 12-13 and 48-60 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Boddie and Aigner (Ans. 3).

2. Claims 10-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Boddie and Aigner (Ans. 6).

3. Claims 61-64 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Boddie, Aigner and Sterman (Ans. 8).

ISSUE

Has the Examiner provided sufficient evidence and technical reasoning to show that the combination of Boddie and Aigner, or the combination of Boddie, Aigner and Sterman, render obvious a system as called for in Appellant's claims comprising a collection conduit seal that occludes a downstream channel?

ANALYSIS

The rejection of claims 1-13 and 48-60 over Boddie and Aigner

Each of these claims require a collection conduit in a downstream channel, the collection conduit having "a collection seal" for occluding fluid flow in the downstream channel. The Examiner relies on Boddie for all the claim limitations except that Boddie fails to disclose "collection seals having a dimension to occlude such as elastomeric balloons" [1] (Ans. 5). However,

[1] Boddie expresses a preference for a ligature to occlude blood flow into the liver (Boddie 3:40-42).

the Examiner states that "it would have been obvious to substitute balloons for the ligatures of Boddie" since "balloons on catheter shafts are well known in the catheter art to effectively, less-invasively and safely occlude blood vessels. This is clearly taught by Aigner" (Ans. 5).

For purposes of discussion, the Examiner identifies Boddie's catheter 34 and branches 35 and 36 inserted upstream the liver as the corresponding "delivery conduit" and the Examiner identifies Boddie's catheter 41 and internal tube 61 inserted downstream the liver as the corresponding "collection conduit" (Ans. 4-5, 10). Consistent with Boddie's teachings, the Examiner only identifies a vessel occlusion associated with an upstream channel (i.e., branch 35) and not any downstream channel as claimed (Ans. 3). Boddie expressly teaches that the occlusion be "disposed upstream of the location of the first branch catheter **35**" (Boddie 3:17-21 and Fig. 3).

Appellant addresses this upstream/downstream occlusion discrepancy stating that Boddie's "ligature is associated with a delivery conduit as identified by the Patent Office, not a collection conduit" as claimed (Reply Br. 3). Appellant contends that to "substitute a balloon for the ligature preferred by Boddie, one presumably would have to branch first branch catheter 35 in a direction downstream (toward the liver) and a position upstream" toward the occlusion (App. Br. 12, *see also* Reply Br. 3). Appellant contends that such "a branch device is far beyond the teachings of Aigner or Boddie" and that additional hardware would be required "to contain the balloon catheter portion" (App. Br. 12, *see also* Reply Br. 3).

The Examiner reiterates Aigner's preference for a balloon to occlude a vessel over a ligature when adjacent an organ (Ans. 11-12) and even presuming that Boddie's ligature is replaced with Aigner's balloon, the

occlusion is still in Boddie's upstream channel and not the claimed downstream channel. The Examiner does not provide any explanation that the location of Boddie's occlusion can be moved from its present upstream channel location to the claimed downstream channel location and still function for its intended purpose (App. Br. 12, Reply Br. 3). Furthermore, as far as we can tell, should either of Boddie's downstream collection conduits 41 or 61 occlude blood flow, the blood flow intended for the patients' heart or the heart-lung machine would be blocked and fluid flow to/from Boddie's liver would no longer be isolated from the rest of the body as intended (*see* Boddie 1:11-15, Fig. 3). Absent such a showing and because the Examiner has not provided a reason that a person of ordinary skill in the art would have occluded Boddie's collection conduit, the Examiner's rejections of claims 1-13 and 48-60 lack a rational underpinning. Accordingly, we are not persuaded by the Examiner's rationale that the substitution of Aigner's balloon catheter for Boddie's ligature would make a collection conduit occlusion seal obvious. In view of the record presented, we reverse the Examiner's rejections of claims 1- 13 and 48-60.

The rejection of claims 61-64 over Boddie, Aigner and Sterman

Dependent claims 61-64 are rejected over Boddie, Aigner and Sterman (Ans. 8). Sterman is cited by the Examiner for its disclosure of a method for accessing the heart and includes placing a catheter into the aorta via the femoral artery and placing a catheter into the coronary sinus via the jugular vein (Ans. 8). Sterman is not relied on nor does it overcome the deficiencies of the combination of Boddie and Aigner *supra*. Accordingly, for the reasons set forth above, we reverse the Examiner's rejection of claims 61-64.

CONCLUSION

The Examiner has not provided sufficient evidence and technical reasoning to show that the combination of Boddie and Aigner, or the combination of Boddie, Aigner and Sterman, teach a collection conduit seal that occludes a downstream channel.

DECISION

The rejection of claims 1-13 and 48-64 is reversed.

REVERSED

MP